

**Amendments to the Drawings:**

The attached REPLACEMENT SHEET of drawings includes a minor change to FIG. 7. This REPLACEMENT SHEET replaces the original sheet including FIG. 7, as filed.

Attachment: one REPLACEMENT SHEET

## REMARKS

Non-elected claims 1-14, 31 and 32 have been canceled, and new claims 34-45 have been added. No new matter was added. New claims 34-45 are directed to the elected balloon catheter invention. Thus, claims 21-24 and 33-45 are pending for prosecution in the present application.

Non-elected and withdrawn method claims 15-17 remain in the application for possibility of rejoinder. To this end, Applicants respectfully request rejoinder of method claims 15-17 should a claim to the structure of a balloon catheter used in the method be allowed.

Based on the amendments and arguments provided herein, Applicants respectfully submit that the claims of the present application are in condition for allowance.

### I. Claim Rejection - 35 USC §102(b)

*In the non final Office Action dated July 30, 2008, claims 21-24 are rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,320,605 issued to Sahota.*

Sahota discloses a dilation catheter that is used to widen a restricted blood flow passage. More specifically, Sahota discloses a dilation catheter for use in a procedure known as Percutaneous Transluminal Coronary Angioplasty (PTCA) for treating a patient having a stenosis (narrowing or constriction of the diameter of a bodily passage). During a PTCA procedure, the dilation catheter is used to increase the lumen by radial expansion of a balloon. See column 1, lines 5-20 and column 5, line 66, to column 6, line 36, of Sahota.

FIG. 1 of Sahota illustrates a single-lobed dilation balloon and FIGs. 4-7 of Sahota illustrate a “multi-lobed” dilation balloon. Column 7, lines 9-49, of Sahota provides a

description concerning the multi-lobed embodiment. As best stated on column 7, lines 15-22, of Sahota:

“The thick portions 34 do not expand as readily as the thin portions 36, and thus the dilation balloon 32 exhibits multiple lobes, having areas corresponding to the thin portions 36 which readily expand to dilate stenotic areas, and areas corresponding to the thick portions 34 which are resistant to expansion, so as not to straighten arterial bends while the lumen is being dilated.”

Sahota clearly teaches that the lobes expand to dilate stenotic areas, while the segments of the dilation balloon of reduced diameter between each pair of lobes are provided for the purpose of preventing undesired straightening of arterial bends when the balloon is inflated. Thus, the sections 34 of reduced diameter provide the balloon with flexible pivot points about which the balloon can be bent to accommodate curves in arterial bends and to prevent such bends from straightening as a result of balloon inflation. Accordingly, Sahota teaches-away from a balloon dilator that is not provided with areas of reduced diameter that function as flexible pivot points for the balloon.

Turning to the present invention, it relates to an internal occlusion balloon catheter for occluding blood flow through a patient's aorta or vena cavae during a procedure when a macromolecular complex is being infused into a venous microstructure of a patient. The purpose of the catheter of the present invention is not to dilate a stenosis; rather, it is to facilitate delivery of desired complexes to target host cells while minimizing side effects (such as by eliminating exposure of other non-targeted areas of the body to the complex, such as the liver or lung).

Due to the difference in use of the catheter of the present invention relative to the dilation catheter of Sahota, there are clear structural differences. As an example, the balloon catheter of the present invention, as best illustrated in FIGs. 1 and 2 of the present application, as filed, has a

balloon or series of balloons that forms an elongate, continuous tube when inflated. The tube formed by the inflated balloon or balloons has a substantially constant outer diameter throughout the full length of the tube. See page 20, lines 30-31; page 23, lines 16-19; page 25, lines 24-26; and page 27, lines 26-27, of the present application, as filed. Also, see FIGs. 3, 4 and 6 of the present application, as filed.

Accordingly, independent claim 21 of the present application has been amended to require the balloon or balloons, when inflated, to form an elongate, continuous, cylindrical tube having an outer diameter that is constant along a full length of the tube. The outer diameter is required to be sufficient to abut the walls of a vessel in which it has been inserted to occlude blood flow therethrough. No new matter was added; for instance, see the sections of the present application noted above.

It is well established that a claim of a patent application is anticipated under 35 USC §102 only if each and every element is found described in a single prior art reference. The identical invention must be shown in as complete detail as contained in the claim. The elements identified by the reference must be arranged as required by the claim.

With respect to the limitations of independent claim 21, as amended, Sahota fails to disclose a balloon that forms an elongate, continuous, cylindrical tube having an outer diameter that is constant along a full length of the tube and fails to disclose a balloon having a constant outer diameter that is sufficiently large to abut the walls of a vessel in which it has been inserted to occlude blow flow. Sahota discloses a lobed balloon for dilating a stenotic area. No embodiment of Sahota discloses, teaches or suggests a balloon that forms an elongate, continuous, cylindrical tube having an outer diameter that is constant along a full length of the

tube. Rather, Sahota teaches a “football” shaped single lobe (FIGs. 1 and 2) and multi-lobed balloons having areas of reduced diameters (FIGs. 4-7). In fact, Sahota teaches-away from a balloon that does not have areas of reduced diameters because a key detail of Sahota is the provision of flexible pivot points along the length of the balloon to prevent undesired straightening of arterial bends. Finally, Sahota teaches, suggests and discloses a balloon that widens a stenosis, not a balloon that occludes blood flow.

For all the above reasons, Applicants respectfully submit that independent claim 21 and dependent claims 22-24 are not anticipated by Sahota. Accordingly, Applicants respectfully request reconsideration and removal of the anticipation rejection of claims 21-24.

## **II. Claim Rejection - 35 USC §103(a)**

*In the non final Office Action dated July 30, 2008, claim 33 is rejected under 35 USC §103(a) as being obvious over U.S. Patent No. 5,320,605 issued to Sahota.*

The prior art Sahota reference, the differences between the claims of the present application, as amended, and Sahota, and the fact that Sahota teaches-away from the balloon catheter as now claimed, are discussed above in detail. For all these reasons, Applicants respectfully submit that independent claim 21 is patentable over Sahota. Accordingly, Applicants respectfully request reconsideration and removal of the obviousness rejection of dependent claim 33.

New claims 34-45 provide additional limitations and reasons for patentability over Sahota.

For example, claims 34 to 41 are directed to a balloon catheter for occluding a patient's aorta. No new matter was added; for instance, see FIGs. 1-4 and 7; page 19, line 25 to page 20, line 10; and pages 20-29 of the present application, as filed. More specifically, see page 21, lines 14-16; page 22, lines 12-13; and page 26, lines 1-4 for the subject matter of claim 34, and see page 22, lines 13-17, for the subject matter of claims 35-37. Also, see page 24, line 9, and page 27, lines 24-25, for the subject matter of claim 38, and see page 22, lines 18-19, and page 27, line 26, to page 28, line 6, for the subject matter of claim 39. Further, see page 23, lines 12-13, and FIG. 1 for the subject matter of claim 40, and see page 23, lines 16-21, and FIG. 2 for the subject matter of claim 41.

Claims 42 to 45 are directed to a balloon catheter for occluding a patient's vena cavae. No new matter was added; for instance, see FIGs. 5-7 ; page 19, line 25 to page 20, line 10; and pages 20-29 of the present application, as filed. More specifically, see page 26, line 9-15, and page 27, lines 7-10 and 13-16, for the subject matter of claim 42, and see page 26, lines 16-23 for the subject matter of claim 43. Also, see page 24, line 9, and page 27, line 17-25, for the subject matter of claim 44, and see page 28, lines 7-15, for the subject matter of claim 45.

Applicants respectfully submit that claims 34-45 are patentable over Sahota.

### **III. Minor Corrections to FIG. 7 and Specification**

The paragraph on page 19, line 25, to page 20, line 10, of the present application, as filed, has been corrected. As filed, this paragraph refers to the "coronary sinus catheter" and a "left pulmonary vein" with reference number "29". Reference numeral "29" correctly applies to the catheter, and reference numeral "39" applies to one of the left pulmonary veins. No new matter

was added. For example, see the left pulmonary vein identified with reference 39 in FIG. 7 of the present application, as filed.

In FIG. 7, as filed, reference numeral "29" merely points to a location. Accordingly, FIG. 7 has been revised to show a box representing the coronary sinus catheter referenced on page 19, line 30, to page 20, line 4, of the present application, as filed. No new matter was added.

#### **IV. Conclusion**

In view of the above amendments and remarks, Applicants respectfully submit that the rejections stated in the Office Action have been overcome. A favorable action on the merits is therefore requested.

Please charge any deficiency or credit any overpayment for entering this Amendment to our deposit account no. 08-3040.

Respectfully submitted,  
Howson & Howson LLP  
Attorneys for Applicants

By \_\_\_\_/William Bak/  
William Bak  
Reg. No. 37,277  
501 Office Center Drive  
Suite 210  
Fort Washington, PA 19034  
(215) 540-9216